UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC., et. al.

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

PLAINTIFF'S RESPONSIVE BRIEF ON CLAIM CONSTRUCTION ISSUES FOR MARKMAN HEARING

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I. INTRODUCTION

On September 8, 2022, the Parties to the above captioned matter filed simultaneous opening claim construction briefs. Both parties presented their positions on disputed claim terms. At issue in this matter are claims 1, 2, 6, and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent"). The parties had exchanged proposed claim term constructions on July 21, 2022 (Plaintiff) and on August 17, 2022 (Defendant)

In its opening brief, Defendant BlueWillow Biologics, Inc. ("BlueWillow") alleged that various terms appearing in claims 1 and 2 are "indefinite." Citing U.S. Supreme Court precedent, BlueWillow stated that, "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). In its opening claim construction brief, Plaintiff and patent owner, Trutek Corp. ("Trutek"), presented arguments demurring BlueWillow's allegations of indefiniteness of the disputed claim terms.

The disputed claim terms in claims 1 and 2 are:

- ***electrostatically inhibiting,***
- ***electrostatically attracting,***
- ***adequate impermeability,*** and
- ***render*[*s*]*** ***said particulate matter harmless.***

On Page 16 of its opening brief, BlueWillow presented the following table comparing BlueWillow's and Trutek's proposed construction of the preambles of claims 1 and 2 of the '802 Patent.

Claim Term	BlueWillow's Construction	Trutek's Construction
"A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue	Preamble is limiting; plain and ordinary meaning, no further construction necessary.	Claim 1 is a method claim, which recites preventing an individual from becoming infected from inhaling harmful airborne contaminant particles.
of nasal passages of the individual in a thin film, said method comprising" (claim 1)		A formulation, which exhibits a static electrical charge, is applied to the individual's nostrils, and it forms a statically charged thin film thereon.
"A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation once applied (Claim 2)	Preamble is limiting; plain and ordinary meaning, no further construction necessary.	A formulation, when applied to a person's nostrils, forms a thin film therein and prevents that person from inhaling harmful airborne particles. The formulation contains at least one cationic agent. A cationic agent produces a positive electrostatic charge. The formulation also contains a biocide.

On Page 20, BlueWillow next posted a table comparing construction of the remaining terms:

Claim Term	BlueWillow's Construction	Trutek's Construction
"a) electrostatically attracting the particulate matter to the thin film" (claim 1)	Plain and ordinary meaning, no construction necessary.	The formulation's electrostatically charged thin film attracts oppositely charged harmful particles.
"b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by allowing the cohesion of the formulation to provide adequate impermeability to the thin film; and" (claim 1)	Plain and ordinary meaning, no construction necessary.	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film captures and holds the harmful particles (that were attracted to it) in place.
"c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless" (claim 1)	Plain and ordinary meaning, no construction necessary.	The formulation contains at least one ingredient that inactivates the captured harmful particles and renders them harmless.
"a) electrostatically attracts the particulate matter to the thin film" (claim 2)	Plain and ordinary meaning, no construction necessary.	Oppositely statically charged harmful particles are attracted to the formulations thin film.

Claim Term	BlueWillow's Construction	Trutek's Construction
"b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film"	Plain and ordinary meaning, no construction necessary.	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film captures and holds the harmful particles (that were attracted to it) in place.
"c) inactivates the particulate matter and renders said particulate matter harmless." (claim 2)	Plain and ordinary meaning, no construction necessary.	The biocide in the formulation inactivates the captured harmful particles and renders them harmless.
"the at least one cationic agent is Benzalkonium Chloride." (claim 6)	Plain and ordinary meaning, no construction necessary.	The "at least one cationic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known cationic agent.
"the at least one biocidic agent is Benzalkonium Chloride." (claim 7)	Plain and ordinary meaning, no construction necessary.	The "at least one biocidic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known biocidic agent.

In a footnote on Page 20, BlueWillow stated, "[f]or clarity, Blue Willow's statement that plain and ordinary meaning applies and no further construction is necessary applies to the remainder of the claim language apart from the terms above that Blue Willow contends render the claims indefinite." Yet, BlueWillow appears to understand construction of each claim itself as a whole by stating that "no further construction is necessary."

Trutek contends that based on claim construction principles, in light of the specification and prosecution history, all claim terms are definite and unambiguous and allow a person having ordinary skill in the art to understand the scope of the claims. Moreover, in light of the specification, claims, and prosecution history, a person of ordinary skill would be able to make and use the invention. 35 U.S.C. §112(a) and 35 U.S.C. §112(b).

Trutek agrees with BlueWillow that "[i]ndefiniteness is a question of law 'inextricably intertwined with claim construction,'" citing *Atmel Corp. ,v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999).

Trutek respectfully submits its responsive claim construction brief, the purpose of which is to respond to arguments and allegations made by BlueWillow in its opening brief regarding the disputed claim terms. It will not repeat any material unless it is associated with arguments and allegations presented by BlueWillow in its opening brief.

The Court filing of BlueWillow's opening claim construction brief is accompanied by a declaration by BlueWillow's expert, Dr. Mansoor M. Amiji ("Amiji"). Amiji's declaration is extrinsic evidence, which should be given less weight than the intrinsic evidence To the extent that Amiji will be permitted to offer testimonial evidence, Trutek's counsel should have the right of cross-examination. In rebuttal to Amiji's declaration, Trutek submits

herewith a declaration of its own expert, Edward A. Lemmo, Ph.D. ("Lemmo"). (Exhibit A). Dr. Lemmo has 46 years in the pharmaceutical industry in which he managed development of products similar to those disclosed in the '802 Patent. In his declaration, Lemmo disagrees with positions taken by BlueWillow in its opening brief as well as opinions expressed by Amiji. His arguments will be addressed in this brief.

II. ARGUMENT

A. PERSON HAVING ORDINARY SKILL IN THE ART

To determine the qualifications of a person having ordinary skill in the art ("person of ordinary skill" or "PHOSITA")[1], one must first determine the level of ordinary skill. This varies based on the purpose for such a determination. The person of ordinary skill appears in 35 U.S.C. §103.

> *A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to* ***a person having ordinary skill in the art to which the claimed invention pertains****. Patentability shall not be negated by the manner in which the invention was made.*[2]

[1] A **P**erson **H**aving **O**rdinary **S**kill **I**n **T**he **A**rt is often referred to a **PHOSITA**, *i.e.*, the acronym formed from the first letter of each of the words. This is a common reference.
[2] Emphasis added.

The person of ordinary skill in § 103 is utilized to determine whether a claimed invention is obvious over the prior art. However, this is not relevant to the task at hand. However, the Federal Circuit defined the characteristic properties of a person of ordinary skill.

> *The person having ordinary skill in the art "is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. Factors that may be considered in determining level of skill include: type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field."*

Custom Accessories Inc. v. Jeffrey Allen Indus., 807 F.2d 955 (Fed. Cir. 1986).

However, determination of whether the claims of the '802 Patent are obvious over the prior art is not at issue in claim construction. 35 U.S.C. §112(a) states:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as* ***to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same****, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.*[3]

Here, § 112(a) is more in line with the purpose of determining the level of ordinary skill. A person of ordinary skill must have the ability to make and use the invention. Finally, according to the Supreme Court holding in

[3] Emphasis added.

Nautilus at 901, a patent claim is indefinite, if when "read in light of the specification delineating the patent, and the prosecution history, [the claim] fail[s] to inform with reasonable certainty, those skilled in the art about the scope of the invention." Thus, the person of ordinary skill is a hypothetical person, who is (1) active in the field, (2) familiar with all the pertinent prior art in the field, (3) has the skill to solve problems in the field, (4) is able to read a patent and understand it to be able to make and use the invention disclosed therein, and (5) is able to understand the scope of the invention as recited in the claims.

However, in *Schneider (Europe) AG v. SciMed Life Sys., Inc.*, 39 USPQ 2d 1596, 1597 (quoting *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985)), the Court held:

> *A person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patent, and often expensive systematic research or by extraordinary insights, it makes no difference which.*

Therefore, the person of ordinary skill does not have the skill of an inventor or innovator. He is merely a technician who has acquired his ordinary skill from education and experience.

To ascertain the level of skill of the person of ordinary skill, one must first look to what kind of person normally works in the relevant field and

would normally read and understand a patent's language so as to be able to make and use the claimed invention. This person, by education or experience would be very familiar with the tools of his trade.

Relevant to the claims of the '802 Patent, the person of ordinary skill must have the ability to create the formulations disclosed in the patent. Such a person is a pharmaceutical formulator. However, he or she is not a developer or an inventor. A developer or and inventor would be a person having extraordinary skill in the art.

Here, extrinsic evidence becomes important because the person of ordinary skill is not described in either the patent itself or the prosecution history. We then should turn to the declarations of Lemmo and Amiji. Lemmo has worked in the field of new product development for 46 years. Throughout his career, he supervised formulators. According to Lemmo:

> *The person of ordinary skill would not have read the '802 Patent stand-alone. Based on his knowledge and experience, this person would be familiar with all the ingredients listed in the ten formulations shown in the '802 Patent. He would have the skill and experience to duplicate those formulations once having seen their list of ingredients. He must know enough chemistry and biology to be familiar with cationic agents and biocidic agents. He must have knowledge of the various airborne "harmful particles," such as bacteria, viruses, pollen, and other allergens. He must know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion. to that end, he needs familiarity with ingredients that are surfactants, thickeners, and binders.*

Decl. Lemmo, ¶17.

> *Based on my knowledge and experience, it is my opinion that this person of ordinary skill need not possess an advanced degree. Further, he does not even need to possess an undergraduate degree. He must be a technician with several years of experience as a formulator. The key requirement is his acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 Patent.*

Decl. Lemmo, ¶18.

By contrast, Amiji states that his person of ordinary skill "would be someone who had ***at least*** an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation." [4] A person with an M.S. degree (or higher) in chemical engineering or pharmaceutical sciences, who is employed in the industry would be expected to innovate. He would be hired as a person having extraordinary skill. (*Decl.* Lemmo, ¶17.) He would be expected to have the skill set to be a developer.

Amiji's allegations that his person of extraordinary skill would not understand the scope of the claims are confusing in light of Lemmo's assertions (based on his experience directing pharmaceutical formulators in product development) that a person of ordinary skill with fewer qualifications would comprehend the scope of the claimed invention.

[4] Emphasis added.

B. SPECIFICATION OF INGREDIENT COMPOSITION BY RANGES

"Generally, the recitation of specific numerical ranges in a claim does not raise an issue of whether a claim is definite." MPEP § 2173.05(c).[5] Disclosure of an invention usually includes multiple embodiments of a claimed invention. This is the case in the '802 Patent. The specification discloses ten example formulations. However, some of the ingredient concentrations of these formulations are given as numerical ranges. Yet, as long as the ingredient concentrations are all held within the range limitations, the ten specific embodiments will function as described in the specification and in the claims. BlueWillow refers to the tables listing the ten embodiments as a "laundry list." However, this slur is an attempt to diminish the importance of disclosing the various embodiments of the invention. These are working formulations, albeit having been disclosed broadly. The names of all ingredients are disclosed. Depending upon the specific requirements of the efficacy of a particular use for the composition, an experienced pharmaceutical formulator would have the necessary skills to optimize the ingredient concentrations. The caveat is that the concentrations should not

[5] The acronym MPEP means the USPTO Manual of Patent Examining Procedure.

fall outside the specified ranges. As Lemmo stated, "Formulators do this all the time. It is not 'rocket science.'" (*Decl.* Lemmo, ¶42.)

In its opening claim construction brief on Page 8, BlueWillow's counsel stated, "there are no examples, data or test results demonstrating that any of the formulations "electrostatically attract" harmful particulate matter to the thin film, as opposed to other negatively charged particles that are not harmful (such as dust). Nor are there any examples, data or test results demonstrating that the claimed formulations "electrostatically inhibit" the harmful particulate matter from infecting an individual." However, a patent does not require disclosure of data or test results. Nor is a patent required to be a manufacturing specification. Given that most harmful particles have negative electrostatic charges and that the cationic agent in the '802 Patent formulations creates a positive electrostatic charge, basic physics dictates that the formulations electrostatically attract said harmful particles.

BlueWillow continues, "the '802 Patent is silent as to the specific charge density or other quantitative parameters needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective."

This also is not a requirement to be imposed on the '802 Patent specification. "A patent specification is not intended nor required to be a production specification." *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536 (Fed. Cir. 1987).

In Paragraph 44 of his declaration, Lemmo stated, "[b]ased on my experience in the pharmaceutical industry, it is my opinion that a formulator having ordinary skill would be able to duplicate the claimed embodiments with nothing more than the '802 Patent to guide them. Further, I do not find Amiji's assertion credible that his person having extraordinary skill would be unable to do what I found that a person of ordinary skill could accomplish."

C. THE DISPUTED CLAIM TERMS

1. Electrostatically Attracting

The word, "electrostatically," refers to "static electricity" and utilizing electrically charged particles. *Merriam-Webster Dictionary*. The Summary of the Invention Section of the '802 Patent Specification (at 3:32-3:40) refers to "an electrostatically charged composition ... when applied to a surface, creates an electrostatic field." It is well known that in an electrostatic field, oppositely charged particles attract each other, and similarly charged particles repel each other.

In claim 1, the term used is "electrostatically attracting," while in claim 2, the term used is, "electrostatically attracts." As discussed *supra*, opposite statically charged particles attract each other. Here, once applied, the formulation exhibits a static charge, while the "harmful particles" exhibit an opposite charge. Thus, the applied formulation attracts the harmful particles. The Summary of the Invention section of the Specification discloses (at 3:35-3:38) that the "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped ..."

The term "electrostatically attracting" refers to that well-known scientific principle. The specification describes a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped."

BlueWillow argues that while the '802 Patent specification lists "ingredients and formulations form making 'electrostatically charged' nasal products, there are no examples, data or test results demonstrating that any of the formulations 'electrostatically attract' harmful particulate matter to the thin film as opposed to other negatively charged particles that are not harmful

(such as dust)." As discussed *supra*, this is not a requirement for a patent specification, and it is irrelevant to construction of the term, "electrostatically attracting." Electrostatic attraction is a basic principle of physics known even by high school students. If harmful particles are negatively charged and the formulation's thin film is positively charged, one does not need test data to prove that the harmful particles will be attracted to the thin film. And, what is the relevance of whether the thin film also attracts dust particles? The lack of test data is not relevant to the meaning of the term. What is relevant is whether a person of ordinary skill would be able to discern the scope of the claimed invention in light of the specification and prosecution history. If he can do so, then the claim is not indefinite by use of that term. According to Lemmo, a person of ordinary skill would be able to do this. (*Decl.* Lemmo, ¶50).

2. Electrostatically Inhibiting

The word, "inhibiting," means (1) to prohibit from doing something or (2) to hold in check. *Merriam-Webster Dictionary*. The preambles of claims 1 and 2 refer to "electrostatically inhibiting harmful particulate matter from infecting an individual..." The meaning of this expression in the claims is using an electrostatic field to attract or repel harmful particles. The recited formulation then prohibits the harmful particles from infecting the individual

through inhalation. The Abstract of the Specification states that microorganisms coming in contact with the substrate or skin are rendered less harmful. The Summary of the Invention section discloses (at 3:35-3:40) that the "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless."

The term "electrostatically inhibiting" is taken from the specification to mean that, "the formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto, and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless." ('802 Patent at 3:35.)

Originally submitted independent claims 1, 2, and 8 of the subject patent application used the term "electrostatically preventing." In a USPTO office action dated August 25, 2011, the Examiner rejected these claims under 35 U.S.C. §112, First Paragraph. The Examiner stated:

> *Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus*

> *the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.*
>
> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.*

A copy of the USPTO Office Action of August 25, 2011 is attached to Trutek's Opening Claim Construction Brief as Exhibit C (ECF No. 37). There is no question that the USPTO patent examiner understood the term when he stated that, "the concept thereof clearly finds support therein when the specification's teachings are taken as a whole."

3. Adequate Impermeability

The dictionary definition of ***impermeability*** is "not permitting passage (as of a fluid) through its substance." (*Merriam-Webster Dictionary*.). The dictionary definition of ***adequate*** is "sufficient for a specific need or requirement." (*Id.*) Claims 1 and 2 state specific "needs and requirements."

The term ***adequate impermeability*** must not be read out-of-context. The term appears in Element (b) of claims 1 and 2. The preamble of method claim 1 states in part, "... *inhibiting harmful particulate matter from infecting*

an individual through nasal inhalation wherein a formulation is applied to the nasal passages of the individual in a thin film ..." Element (b) of claim 1 states in part, "... *holding the particulate matter in place ... by adjusting the cohesion of the formulation to provide adequate permeability to the thin film* ..." Finally, Element (c) states the purpose of the claim as, "... *render said particulate matter harmless.*"

The preamble of formulation claim 2 and claim Elements (b) and (c) state similar needs and requirements as claim 1, above.

Thus, ***impermeability***, as used in the claims, refers to the thin film inhibiting harmful particles from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. Further, ***impermeability*** refers to the ability of the thin film to hold captured harmful particles in place by adjusting the adhesion and cohesion of the formulation's thin film. This holding function is critical to the invention, and "impermeability" is a part of this function. The thin film is rendered tacky or sticky so that harmful particles adhere to it and do not dislodge into the air stream to be inhaled by the individual. ('802 Patent at 3:2.) The adhesion and cohesion is adjusted by varying the concentrations of ingredients (such as a surfactant, a thickener, and a binder (*Id. at* 5:9-13)). Thus, by adjusting the adhesion and cohesion of the thin film, the formulation becomes impermeable, allows the harmful

particles to adhere to the thin film, thereby preventing inhalation of harmful particles. Here, the term "impermeable" takes on its plain and ordinary meaning. This would be understood by a person of ordinary skill. (*See Decl.* Lemmo, ¶52)

The term "**adequate impermeability**" uses a term of degree (*i.e.*, adequate). "Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (citing *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923) (finding "substantial pitch" sufficiently definite because one skilled in the art 'had no difficulty ... in determining wheat was the substantial pitch needed' to practice the invention.)). The phrase "an effective amount . . .for growth stimulation" was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911 (C.C.P.A. 1970). Thus, when a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree. *Hearing Components, Inc. v. Sure Inc.*, 600 F.3d 1357, 1367 (Fed. Cir. 2010); *Enzo Biochem, Inc. v. Appelera Corp.*, 399 F.3d 1325, 1332

(Fed. Cir. 2010); *Seattle box Co., Inc. v. Crating & Packaging, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984). Here, the specification of the '802 Patent provides ten examples (Tables 1 - 10) of formulations that all function as in the claims. The formulations each contain ingredient compositions, the concentrations of which are given in ranges. The actual ingredient concentrations need to be adjusted by a person of ordinary skill (*i.e.*, a formulator) to have the desired characteristics of adhesion of the thin film along with its tackiness to capture and hold the harmful particles, thus providing adequate impermeability. While this would require some experimentation, for a person of ordinary skill, that experimentation would not be undue. Further, as indicated in the USPTO office action of August 25, 2011, the examiner considered whether, and in allowing the application, determined that the claims, as a whole, would enable a person of ordinary skill "to make and use the invention as commensurate in scope with these claims."

4. Render[s] Said Particulate Matter Harmless

The "Objects Of The Invention" Section of the specification of the '802 Patent informs the reader of several requirements of the disclosed invention:

> *It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.* ('802 Patent at 2:62.)

It is another object of the invention to have the capability to hold it for a duration from being dislodged in to the air stream again. (*Id.* at 3:1.)

It is a further object of the invention to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition. (*Id.* at 3:4.)

It is still another object of the invention to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents. (*Id.* at 3:19.)

And the Abstract of the '802 Patent states:

The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

The examiner in USPTO Office Action of August 25, 2011 stated:

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host (*see MPEP §2113; terms given their broadest reasonable interpretation*), *may be prevented,* (*which again, given its broadest, reasonable interpretation*), *i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmacological composition while an effective prevention against the introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host be completely blocked so as to preclude any infectious material passing though such system of the host.*

> *In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be* ***inhibited*** *rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host*.

Here, from the specification and the prosecution history, it is apparent what is meant by "render[s] said particulate matter harmless." The claimed formulation (1) forms an impermeable thin film that adheres to the skin or tissue of the nasal passages; (2) contains a cationic agent that attracts harmful particles; (3) holds those harmful particles in place because they adhere to the thin film; and (4) contains a biocide, which "neutralizes, inactivates, kills, or renders harmless a microorganism, which has been captured and held by the composition." Rendering a microorganism harmless equates to it being neutralized, inactivated, or killed. However, based on the prosecution history (amending the term "preventing" to "inhibiting"), rendering said particulate matter harmless does not require all harmful particulate matter to be neutralized, inactivated, or killed.

D. INDEFINITENESS AND INVALIDITY

BlueWillow cited *Nautilus*, 572 U.S. at 901, stating that, a "patent is invalid for indefiniteness if its claims, read in light of the specification

delineating the patent, and the prosecution history, fail to inform with reasonable certainty, those skilled in the art about the scope of the invention." BlueWillow further stated that, "[t]he burden of establishing invalidity based on indefiniteness rests on the party asserting invalidity and must be proven by clear and convincing evidence." Citing *Takeda Pharm. Co. v. Zydus Pharms, USA, Inc.*, 743 F.3d 1359, 1366 (Fed. Cir. 2014). Then, BlueWillow cited *Nautilus* once again stating that indefiniteness is measured from the perspective of a person of ordinary skill at the time the patent was filed. On Page 8 of its Opening Brief, BlueWillow criticized the '802 Patent for not providing any information concerning the "objective parameters" a person of ordinary skill would need to have. It is extremely rare that any patent would do this.

Because the qualifications of a person of ordinary skill is not discussed either in the specification or the prosecution history of the '802 Patent, it is necessary to turn to the extrinsic evidence to determine that person's qualifications and whether that person has been informed with reasonable certainty "about the scope of the invention." Here, the experts disagree about the qualifications of a person of ordinary skill. Amiji's person of ordinary skill requires more education and experience than Lemmo's person of ordinary skill. However, Lemmo himself has 46 years experience directing the

operations of pharmaceutical and nutritional corporations in new product development. Lemmo labeled Amiji's person as having extraordinary skill in the art, being more qualified as a developer. According to Lemmo, the person having ordinary skill in the art, as defined by him (*i.e.*, a formulator), would be able to comprehend the scope of the claimed invention at the time the patent was filed, and would be able to make and use the claimed formulations with only the '802 Patent as a road map. Lemmo found it incredible that Amiji's person of extraordinary skill could not do what a formulator normally does. As Lemmo stated, "[h]e or she would need to do some experimentation that would optimize the combination of ingredients. Formulators do this all the time. It is not 'rocket science.'" (*Decl.* Lemmo, ¶42.)

Lemmo went on to opine on the disputed claim terms. He did not find them indefinite or ambiguous. Apparently, the patent examiner was of the same opinion when he said, "it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole." BlueWillow criticizes the '802 Patent for not providing test data and guidance how to prepare the formulations included in the specification as embodiments of the invention. BlueWillow expected a step-by-step instruction sheet for making the example formulations. BlueWillow appears to require a detailed production specification. However, this is not required

provided that a person of ordinary skill can make or use the claimed invention without undue experimentation. Some experimentation needs to be performed to optimize the example formulations. According to Lemmo, this task is regularly performed by pharmaceutical formulators.

BlueWillow appears to have understood the scope of the claims as a whole when it said, for each clause in the claims of the '802 Patent, "plain and ordinary meaning, no construction necessary." The words in the claims all take on their plain and ordinary meaning, and the claims as a whole are understandable. As BlueWillow stated *supra*, "[t]he burden of establishing invalidity based on indefiniteness rests on the party asserting invalidity and must be proven by clear and convincing evidence." BlueWillow failed to meet its burden. The '802 Patent is presumed valid by law as are its claims. BlueWillow failed to present clear and convincing evidence to the contrary.

III. CONCLUSION

As argued *supra*, BlueWillow failed to show patent invalidity based on indefiniteness of claims 1, 2, 6, or 7 by clear and convincing evidence. In the conclusion of its Opening Claim Construction Brief, BlueWillow proposes an alternative for the Court in constructing the terms of the claims. BlueWillow suggests that the Court should hold the preambles to be limiting. Trutek

concedes that the preambles limit the scope of the claims to the extent that they breathe life into their claims, which is often not the case. The preambles are the first instances where some elements and terms later used in their claims are defined. The claims themselves would be indefinite under 35 U.S.C. §112(b) if their preambles were not deemed significant. Further, BlueWillow suggests that all the words of the claim terms be given their plain and ordinary meaning. This is contrary to the patent construction process, because claim terms are to be construed based on their use in the specification and prosecution history. Words should be given their plain and ordinary meanings from dictionaries only in the absence of contrary guidance from the specification or prosecution history. However, it should be recognized that their usage in the specification and prosecution history of the '802 Patent is not repugnant to their plain and ordinary meanings. BlueWillow's allegations of indefiniteness should be denied.

Dated: September 27, 2022

Respectfully submitted,

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Attorneys for Plaintiff, Trutek Corp.

Exhibit A

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10,
gender neutral fictitious names,
and ABC CORPORATION 1
through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

DECLARATION OF EDWARD A. LEMMO, Ph.D. IN SUPPORT OF TRUTEK CORP.'S CLAIM CONSTRUCTION BRIEF

I, Dr. Edward A. Lemmo, declare as follows:

1. My name is Edward A. Lemmo. I have been retained as an expert witness by Plaintiff, Trutek Corp. ("Trutek"), in the above captioned matter. I am being compensated for my time spent with regard to this litigation at the rate of $250 per hour. My compensation is not affected by the outcome of this lawsuit.

2. I understand that this legal matter concerns allegations by Trutek that Defendant BlueWillow Biologics, Inc. ("BlueWillow") infringed claims 1, 2, 6, and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent") by making and selling a product called NanoBio Protect.

3. This declaration relates to the issue of claim construction the '802 Patent. I am familiar with the '802 Patent, and I understand the teachings of its patent specification and its claims.

4. For purposes of this declaration, I read and understood:

   a. "Plaintiff's Initial Brief On Claim Construction Issues For Markman Hearing," filed with the Court as ECF No. 37 on September 8, 2022. I also read and understood the exhibits attached to this brief.

   b. "Defendant BlueWillow Biologics, Inc.'s Opening Claim Construction Brief," filed with the Court as ECF No. 38 on September 8, 2022. I also read and understood the exhibits file by BlueWillow along with their brief, namely ECF Nos. 38-2, 38-3, and 38-4.

5. I disagree with the opinions expressed by Dr. Mansoor M. Amiji ("Amiji") in his declaration (filed as ECF No. 38-3). In particular, it is my opinion that:

a. the qualifications stated by Amiji for a person having ordinary skill in the art (a "person of ordinary skill") belong the a person having extraordinary skill in the art (a "person of extraordinary skill").

b. The disclosures of the specification and claims of the '802 Patent enable a person of ordinary skill to understand the claims and to make and use the inventions of claims 1, 2, 6, and 7.

c. Based on the disclosures of the specification and the claims, it is my opinion that the claim terms, "electrostatically inhibiting," "electrostatically attracting," "adequate impermeability," and "render[s] said particulate matter harmless," are sufficiently clear and unambiguous so as to inform a person of ordinary skill "as to the scope of the claimed invention of asserted claims 1, 2, 6, and 7 of the '802 Patent."

d. This declaration presents my opinions, findings and conclusions regarding the disputed terms in the following paragraphs:

- Person Having Ordinary Skill in the Art - Paragraphs 13-18;
- Electrostatically Inhibiting - Paragraphs 25-31 and 48-49;
- Electrostatically Attracting - Paragraphs 34 and 50;
- Adequate Impermeability - Paragraphs 33-35, 37, and 51-54;
- Render[s] Said Particulate Matter Harmless - Paragraphs 30 and 54-55; and
- Claims 1, 2, 6, and 7 (considered as a whole) - Paragraph 56.

QUALIFICATIONS AND EXPERIENCE

6. My *curriculum vitae* is attached hereto as Exhibit A. What follows are highlights of my qualifications to serve as an expert witness in this matter.

7. I have a B.S. in chemistry, an M.S. in Nutrition Science, and a Ph.D. in nutrition science. I was awarded my Ph.D. in 1979.

8. For a long time, I have offered my services as a consumer healthcare corporate consultant. In this capacity I consulted for Nutramerica, Nutrition 21, IVC Industries, Church & Dwight, and Matrixx Initiatives, Inc.

9. I served as Vice President of Product Development for BioBalance Corporation and for Wyeth Consumer Healthcare. I was the Director of Nutritional Sciences for General Nutrition Centers, Inc. I was the Director of Nutritional Technology for ICN Pharmaceuticals, Faraday Laboratories Division. I was Marketing Manager for Pall Biomedical Products, and was Clinical Trials Coordinator for Pharmacia Laboratories.

10. In my experience, I have overseen the development and formulation of pharmaceutical and nutritional products that were sold over-the-counter. I understand the steps of product development, formulation, scaling-up, and manufacturing for pharmaceutical products.

11. I am not an attorney, nor have I had legal training. I understand that the construction of claim terms is a legal matter. I am not qualified to opine on the legal significance of any claim. However, I am familiar with patents, and I have read many of them. I have assisted others in preparing patent applications and I have performed due diligence with respect to

investments in patents. As a scientist, I seek to understand the technology and the plain and ordinary meaning of words contained in the specification (the invention disclosure) and the claims.

12. Based on my education and experience in pharmaceutical product development, I understand the technology disclosed in the '802 Patent, and I am able to opine that the specification and claims of the '802 Patent provide a sufficient roadmap to enable a person of ordinary skill to employ the method in claim 1 and to make the formulation of claim 2. Claims 6 and 7 further specify a particular ingredient to be used in the formulation of claim 2, and its use in that formulation is apparent.

THE PERSON OF ORDINARY SKILL

13. A person having ordinary skill in the art is essentially a fictitious individual considered to have a general or working knowledge of the subject matter in question. The operative word in this context is "ordinary." This is a person who possesses special or distinctive knowledge or capability in a discipline. This person would have a basic skill set or talent related to the technology related to the art. In addition, a person of ordinary skill knows of and understands all the prior art in his field of endeavor prior to the time that he is asked to evaluate the teachings of a patent. He must have sufficient experience in his art so as to be competent to understand and interpret the prior art related to a patent so that he can make and use the invention described and claimed in the patent. A person of ordinary skill is primarily a technician in his chosen field, and his skills are those ordinarily

associated with such a technician. He is not an inventor. However, he is not a robot either. He must be able to understand and interpret the teachings associated with the type of structures and chemical compositions described in a document such as a patent. That document may possess directives for creating a product including the step by step protocol for making or assembling the product. In some instances, a person of ordinary skill may apply his fundamental skills in a procedure to follow instructions provided by a person possessing extraordinary skill. That extraordinarily skilled person may be a person having an advanced degree in a specific discipline who can educate others in that specific skill.

14. Having been a college professor for more than 30 years, I have taught numerous students on basic scientific concepts who were either majors in the discipline or students who were non-majors who wanted to gain a working general knowledge or skill. The students who majored in the discipline would be expected to reach a level of extraordinary skill. Those who were non-majors were not expected to develop extraordinary skill but were expected to have a working knowledge of the subject matter. Hopefully, the example provided takes the imaginary or fictitious person to a real life individual who has a working knowledge of a subject matter and can understand and interpret the subject matter.

15. It is important to determine the level of skill of a person who would be considered a person of ordinary skill with regard to the '802 Patent. It is essential that this person cannot be a person of extraordinary skill. A

person of ordinary skill would not have the same knowledge or motivation to invent as a person having extraordinary skill.

16. In his declaration (ECF No. 38-3) in Paragraph 26 on Page 9, Amiji opined on the level of skill, experience, and education of a person of ordinary skill. He stated that such an individual should have "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team — including a chemical engineer, microbiologist, or polymer chemist — and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem."

17. Having read and understood the teachings of the '802 Patent, I concluded that Dr. Amiji described a person of extraordinary skill in the art and technology of that patent. Instead, the level of skill possessed by a person of ordinary skill is that of a chemical or pharmaceutical formulator. This person would have two related but separate qualifications. First, after reading the '802 Patent, he should be able to create the formulations described in the patent, and then be able to use the formulations as prescribed. Second, the person of ordinary skill must be positioned in time just prior to effective filing date of the '802 Patent. Based on this second requirement, the person of ordinary skill would not have read the '802 Patent stand-alone. Based on his knowledge and experience, this

person would be familiar with all the ingredients listed in the ten formulations shown in the '802 Patent. He would have the skill and experience to duplicate those formulations once having seen their list of ingredients. He must know enough chemistry and biology to be familiar with cationic agents and biocidic agents. He must have knowledge of the various airborne "harmful particles," such as bacteria, viruses, pollen, and other allergens. He must know enough undergraduate physics to understand electrostatic fields as well as the principles of electrostatic attraction and repulsion, adhesion, and cohesion. To that end, he needs familiarity with ingredients that are surfactants, thickeners, and binders.

18. Based on my knowledge and experience, it is my opinion that this person of ordinary skill need not possess an advanced degree. Further, he does not even need to possess an undergraduate degree. He must be a technician with several years of experience as a formulator. The key requirement is his acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 Patent.

THE PRODUCT DEVELOPMENT PROCESS

19. In my experience with product development, the inventor of a new product has an idea based on an observation or on reading literature related to the topic. A product developer may either be the inventor or one who is assigned the task of developing a newly invented product. This person composes ideas and concepts either individually or with a team to construct the framework of the new product. At this stage, the

development process is very generic. Categories of product components are considered rather than exact amounts. The developer is anyone who has the ability or vision to create a new item or improvement of an existing product for the betterment of the user. Basically, this person gets an idea and brings it forward for consideration. The product does not need to be in a final form. This developer is a person of extraordinary skill.

20. From the area of product development, the concept is brought to the second stage of the process. The developer works together with a formulator, who is a person of ordinary skill. He or she takes the idea originally penned by the inventor or developer (either in a task document, a patent application, or an issued patent) and compiles various component ingredients that would meet the needs of the original design and provide options for the finished product. The formulator is usually a person employed in the manufacturing sector or the operations division of a corporation. Many of these formulators have basic working skills developed in the manufacturing facility. As a result of previous experiences, this person can take the concept presented by the inventor or developer, who may be a scientist, and make the product prototypes. The core elements of the product are specified by the inventor or developer to meet the expectations or objectives when using the product.

21. Essentially, the components of the patent may include the skeletal structure or framework of the new product as originally designed by the inventor. If the product requires a binding agent, emulsifier, or any

compositional agent, these would be included in the patent. A person of ordinary skill should be able to read the patent and understand that there are some fundamental components of the patented design and options of these components to create prototypes based on this information. A patent is not a manufacturing specification. It does not need to be written in exact measures for a person of ordinary skill to take the written invention, originally crafted from the inventor's idea, and embellished by the formulator to go forward and develop a product based on this information.

22. In the third stage of the process, the product, while in the prototype phase of development, is now reshaped or focused considering the efficacy of the product. Ingredients may be substituted. Generic ingredients may be utilized. Consideration of ingredient interaction is evaluated. Considerations of product stability is considered for shelf-life and reproducibility. Once again, these actions are preformed by formulators, who are persons of ordinary skill.

23. In the fourth stage, consideration of scaling-up the product in a manufacturing facility is made so that the idea found in the patent with the optional components of each category (*e.g.*, active components, surfactants, thickening agents, flow agents, binders, fillers, excipients, *etc.*) become a finished product that meets the goals of the product's use. Considerations regarding manufacturing are normally handled by

engineers, who may be persons either of ordinary skill or extraordinary skill.

24. The final stage of the process involves bringing the product to market. A pharmaceutical product needs to go through extensive testing ultimately proving that the product is safe and effective for use by humans. Approval by government regulatory agencies is usually required. The product concept originated by the inventor is put to the test to see if the idea can become a reality in the development of the new product. Sales and marketing people put their final touches on the product so that the consumer connects with the inventor's idea on how the new product is of benefit to them.

ENABLEMENT OF THE '802 PATENT

25. The '802 Patent discloses and claims a method for inhibiting harmful particles from infecting an individual through nasal inhalation using an electrostatically charged formulation that attracts those particles, holds them and renders them harmless. It also discloses and claims the formulations and details of example ingredients of such electrostatically charged formulations. Thus, the term, ***electrostatically inhibiting*** is clearly taken to mean inhibiting harmful particles from infecting an individual using an electrostatically charged formulation.

26. It is well known that electrostatically charged particles attract oppositely charged particles and repel similarly charged particles. These are the well-known phenomena of ***electrostatic attraction*** and ***electrostatic***

repulsion, respectively. When applied to any surface, an electrostatically charged formulation typically leaves charged particles on that surface. Thus, such a formulation will attract oppositely charged particles to the surface and will repel similarly charged particles from the surface.

27. For example, most harmful particles (such as microorganisms) are negatively charged. Application of a positively charged formulation to the skin or tissue would cause the harmful particles to be attracted to the formulation (*i.e., via* ***electrostatic attraction***).

28. The formulation disclosed in the '802 Patent is one "that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release ... capable of capturing particulates and microorganisms." ('802 Patent at 2:62.) I call this, "Catch" function.

29. Once applied, the formulation "has the capability to hold it [*i.e., the particulates and microorganisms*] for a duration from being dislodged in the air stream again." (*Id.* at 3:1.) I call this the "Hold" function.

30. Further, the formulation, having held the particulates, is able to "to simultaneously inactivate, kill, or render harmless the microorganisms so trapped." (*Id.* at 3:13.) I call this the "Kill" function.

31. Thus, the method of claim 1 for inhibiting harmful particles from infecting an individual through nasal inhalation using an electrostatically charged formulation is accomplished using the functions of "catch," "hold," and "kill."

32. The '802 Patent expresses the term "hold" in the claim statements related to the multi-action mechanism of the invention. While the product attracts particulate matter from the airflow before entering the nasal passageway utilizing electrostatic forces, this alone is insufficient to protect the individual from harmful particulate matter entering the body's respiratory system. Holding is a protective concept based on adhesive and cohesive properties.

33. **Adhesion** of the formulation can be viewed in two ways: (1) adhesion to the skin of the individual applying the formulation in and around the nasal passageway; and (2) adhesion of the particles in the airflow to the formulation itself. **Cohesion** provides a tackiness that incorporates the concept of adhesion. Adhesion concerns the forces bonding dissimilar molecules together. Cohesion concerns the forces bonding similar molecules together. Adhesion considers particles of opposite charge, while cohesion goes beyond this concept to include particles of like charge. This sets up a **barrier of impermeability** trapping a significant number of these particles outside the nasal passageway.

34. If the formulation is applied to the skin or tissue inside a person's nostrils, the holding function prevents these particles from either being inhaled into the respiratory system or from contacting the skin or tissue directly. Therefore, holding is a critical aspect of the patent claims since the power of the electrostatic forces to attract airborne particles must be enhanced using the principles of adhesion and cohesion. This interaction of the

formulation with foreign particles found in the air, by electrostatically attracting and capturing them and then holding them in place, sets up the opportunity for the formulation's ingredients to inactivate them prior to entry into the respiratory system. The formulation contains a cationic agent to attract bioactive particles such as bacteria, viruses and other biologically harmful particulates found in the air. It also contains a biocidic agent that acts to destroy or neutralize the captured bioactive particles.

35. Essentially, the mechanism of the formulation to carry out the protection it claims to afford the user would be incomplete if the formulation did not have the adhesive and cohesive properties required to hold the particles in place. Attraction by electrostatic forces is enhanced by the holding properties of adhesion and cohesion, and the holding properties set up the formulation's biocidic ingredients to inactivate and kill bioactive particles that are held in place by the formulation.

36. Most harmful airborne particles have a negative electrostatic charge. The formulation is applied to the skin or tissue of the nasal cavities as a thin film. The presence of a cationic agent in the formulation produces a positive electrostatic charge, which attracts and captures the negatively charged particles. A biocide in the formulation would ordinarily be expected to inactivate and kill the captured bioactive particles. But, to be effective, biocidic action requires contact with bioactive particles for a certain time period. If the captured particles happen to dislodge from the formulation's thin film, they would remain active and be inhaled. Even if

they were in contact with the biocide for a sufficient time to be inactivated, the dislodged inactivated particles would still be able to be inhaled. Thus the "hold" function is critical to usefulness of the invention.

37. Thus, **adequate impermeability** is a property of the applied formulation that allows the harmful particles to be held in place for a sufficient time to be inactivated.

38. The specification of the '802 Patent explains the methodology of the invention in the Summary of the Invention section (*Id.* at 3:30) and in the Detailed Description of the Invention section (*Id.* beginning at 3:42).

39. The specification proposes the formulation's generic ingredients:

- water,
- at least one quaternary thickener,
- a preservative,
- a conditioner,
- an emulsifier,
- a biocidic agent,
- a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8.
- a surfactant,
- a thickener,
- an emollient,
- a humectant, and
- a binder

40. Next, the specification provides specific examples of the ingredients listed in the previous paragraph.

41. Then, the specification provides ten example formulations. According to the specification, all of these example formulations function as recited in claims 1, 2, 6, and 7. Defendants have called these ten examples a "laundry list." This characterization diminishes the importance of providing

these examples to a person of ordinary skill. Each example is an embodiment of the claimed invention. In these examples, the ingredient quantities are not provided exactly. The quantities are provided in ranges. As long as the composition of ingredients remains within the specified ranges, the example formulations should function as disclosed. Although some experimentation needs to be performed by the formulator to optimize the formulation to meet the specific requirements of efficacy and stability with regard to its application to the various diseases and conditions enumerated by the tables in Column 4 of the '802 Patent, such experimentation would not be undue.

42. In my experience in product development and having supervised pharmaceutical formulators, who are persons of ordinary skill, virtually any experienced formulator would be able to experimentally optimize a composition of ingredients using the road map set forth by the ten examples. An experienced formulator would be able to create a formulation that performs as in the claims with only the '802 Patent as a road map, and with nothing more. He or she would need to do some experimentation that would optimize the combination of ingredients. Formulators do this all the time. It is not "rocket science."

43. In his expert report (ECF No. 38-3), Amiji defined a person of ordinary skill as having "at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of

ordinary skill in the art may have worked as part of a multidisciplinary team— including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem." In my opinion, this is a person of extraordinary skill.

44. In my experience, formulators of ordinary skill would likely not have the level of education and experience set forth by Amiji. Based on my experience in the pharmaceutical industry, it is my opinion that a formulator having ordinary skill would be able to duplicate the claimed embodiments with nothing more than the '802 Patent to guide them. Further, I do not find Amiji's assertion credible that his person having extraordinary skill would be unable to do what I found that a person of ordinary skill could accomplish.

DISPUTED CLAIM TERMS OF THE '802 PATENT

45. I am not an attorney. I understand that the property of a claim being indefinite is a legal determination, which is in the province of the Court. Therefore, I will not use this terminology. Instead, I will opine on whether the disputed claim terms are sufficiently unambiguous to enable one of ordinary skill to understand and practice the inventions set forth in the claims.

46. In providing my opinions, I realize that I need to place myself into the time period when the application ultimately issuing as the '802 Patent was filed. That priority filing date was July 7, 2008. Based on my experience, it is

my opinion that the qualifications of a formulator of ordinary skill were exactly the same in July 2008 as they are today.

47. Where feasible, I prefer the plain language definitions of the various claim terms. Where there are multiple plain language definitions, I choose the most applicable from among them. However, I also look to the specification of the '802 Patent and the USPTO prosecution history for guidance.

48. **Electrostatically Inhibiting** - to construct this term, one needs to examine its context in the claims. The preamble of claim 1 begins with a "method for electrostatically inhibiting harmful particulate matter from infecting an individual ..." The preamble of claim 2 begins with a "formulation for electrostatically inhibiting harmful particulate matter from infecting an individual ..." These words of the preamble suggest a use for the method and formulation that follow in the claims. The function of the claimed invention is "inhibiting harmful particulate matter from infecting an individual." The meaning of this phrase is clear and apparent. From the remainder of each claim 1 or 2, supported by the specification, the claim elements involve electrostatic fields. Claims 1 and 2 refer to electrostatic attraction, which is a well-known scientific phenomenon even to a high school physics student. Claim 2 requires its formulation to contain a cationic agent, which is known to possess a positive electrostatic charge. Thus it is clear that the term "**electrostatically inhibiting**" in the claims means inhibiting harmful particulate matter from infecting an individual

using the means of creating an electrostatic field. This interpretation is supported by the specification of the '802 Patent.

49. Exhibit 3 of Amiji's declaration (ECF No. 38-4) is a copy of the first USPTO office action affording a non-final rejection to the '802 Patent Application. As originally submitted, the usage term in claims 1 and 2 was "electrostatically preventing." In his office action, the examiner required amending the claim by changing the term "electrostatically preventing" to "electrostatically inhibiting." Clearly, the examiner understood the connotations of this term. The examiner stated:

> *In reading the present specification as a whole, it appears that the tenor thereof is that infections, whether they cause a pathology or not, may be* ***inhibited*** [1] *rather then be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.*

50. **Electrostatically Attracting** - The specification of the '802 Patent is replete with references that explain the meaning of this term. For example, the Abstract states: "The formulation when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate ..." Electrostatic attraction is a well-known fundamental principle of physics. Changing the grammatical usage of the term to electrostatically attracting merely recites what the formulation of claims 1 and 2 is doing. The meaning of this term is apparent and unambiguous.

[1] Emphasis supplied.

51. **Adequate Impermeability** - This term cannot be read out-of-context. It must be read in terms of the "hold" function discussed by me earlier. Claim 1 recites "holding" as a method step, while claim 2 recites that the formulation "holds." The claim element of each claim reads, "[holding/holds] the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film ..." The specification provides that the formulation shall contain a surfactant, a thickener, and a binder.

52. The term, "adequate impermeability" refers to the thin film of the formulation holding harmful particles in place for a duration to prevent them from being dislodged in to the air stream again. ('802 Patent at 3:2.) This is done by varying the concentration of ingredients (such as a surfactant, a thickener, and a binder (*Id. at* 5:9-13), thus adjusting the adhesion and cohesion of the thin film. The particles are held in place by making the thin film impermeable. The adhesion of the thin film is adjusted so that it adheres to the nasal tissue. The cohesion of the thin film is adjusted to make it tacky and sticky. Finally, the harmful particles stick to the thin film until they can be inactivated. Here, the term "impermeable" is given its plain and ordinary meaning. This would be understood by a formulator having ordinary skill.

53. As the concentrations of the ingredients are adjusted, the thickness, tackiness, and stickiness (*i.e.,* permeability) of the thin film changes.

Determination of adequate permeability is a term of degree, and the material composition to accomplish the intended purpose depends on the desired efficacy. The '802 Patent specification provides examples of the ingredients that would affect permeability, and the ten examples provide the ranges of these ingredients that would produce formulations that function as in the claims. Following the road map provided by the patent's specification, adjusting the formulation to provide the desired permeability is straightforward. Once again, this is not "rocket science." This is what formulators do all the time.

54. **Render[s] Said Particulate Matter Harmless** - As discussed earlier, the functions of claims 1, 2, 6, and 7 can be summarized as "catch," "hold," and "kill." (1) Regarding the "catch" function, harmful electrostatically charged particles (including microorganisms) are attracted to the oppositely charged thin film of the formulation that adheres to the skin or tissue of the individual's nasal passages. They are captured by the formulation's thin film. (2) Regarding the "hold" function, the harmful particles stick to the thin film which is tacky and impermeable. They are prevented from re-entering the air stream and into the individual's respiratory system. (3) Regarding the "kill" function, the harmful particles are "held" in contact with a biocide (such as benzalkonium chloride) for a sufficient period to enable them to be deactivated.

55. The term, **"Render[s] Said Particulate Matter Harmless,"** may not be read in a vacuum. It must be read in light of the specification and the

prosecution history of the '802 Patent. This term is discussed in the specification and the claims. The Abstract states, "[t]he electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful." [2] The specification (at 2:6) states that the Present Invention "inactivates" the harmful particles "dermallly outside the body and render[s] them harmless." Further (at 3:12), the specification states, "trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped." Here, the significance of this statement is the correlative conjunction "or." This shows the term, "render harmless," as being equivalent to inactivation and killing. Finally, in the prosecution history, the reasoning behind the examiner's rejection of the word "preventing" in the claims and recommending substituting the word "inhibiting," was to show that, "[t]he former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host." Thus, the term, "render[s] said particulate matter harmless," refers to preventing at least some of the infectious material from passing into the system of the host by inactivating or killing it, thereby rendering it "less harmful." (*See* Abstract.) Even though some particulate matter may be

[2] Emphasis added.

inhaled by the individual, those harmful particles that are held, inactivated, or killed are rendered harmless.

56. Patent claims are often incomprehensible by lay persons because the words and sentence structure are purposed as legal instruments rather than as narratives to be understood by the general public. Claims are long run-on sentences containing words that may be unfamiliar to the layman. Claims are not written with proper English syntax. However, in the case of claims 1, 2, 6, and 7 of the '802 Patent, the words appear to have been given their plain meaning and the clauses are separately enumerated. In my opinion, a person of ordinary skill (*i.e.*, a formulator of pharmaceutical preparations) would be able to read these claims in light of the specification, understand their meanings, and from them he or she would have no difficulty in creating the disclosed embodiment compositions without undue experimentation.

I make this declaration and the statements therein under pains and penalties of perjury under the laws of the United States and the State of Michigan.

Edward A. Lemmo

Dated: September 24, 2022

LEMMO

EXHIBIT A

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EDUCATION

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EXECUTIVE TRAINING COURSES

Executive Leadership Program, Princeton, NJ
Time Management Skills, Teaneck, NJ
Media Communication Skills, New York City, NY

EMPLOYMENT EXPERIENCE

2007-Present **Consumer Healthcare Corporate Consultant**
Self-employed Consultant - Consumer Healthcare

2005-2007 **BioBalance Corporation**, New York, NY
Vice President, Product Development

Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.

1999-2005 **Wyeth Consumer Healthcare**, Leonia and Madison, NJ
Vice President, Product Development

Division of American Home Products
Formerly Whitehall-Robbins Consumer Healthcare

Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999 **General Nutrition Centers, Inc.**, Pittsburg, PA
Director, Nutritional Sciences

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE® zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992 **Pall Biomedical Products**, Glen Cove, NY
Marketing Manager

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989 **ICN Pharmaceuticals**, Costa Mesa, CA
Director of Nutritional Technology

Faraday Laboratories Division

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn® and Sivad Bioresearch®. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977 **Pharmacia Laboratories**, Piscataway, NJ
Clinical Trials Coordinator

Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON® products comprising hyaluronic acid, and their effect on tissues.

CORPORATE CONSULTING EXPERIENCE

2011 **Matrixx Initiatives, Inc.**, Princeton, NJ
Scientific Affairs Consultant

Performed research associated with ZICAM® oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.

1998-1999 **Church & Dwight**, Princeton, NJ
Scientific Advisor

Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metalic agents for use in dietary supplements.

1998-1999 **IVC Industries**, Freehold, NJ

IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.

1996 **Nutrition 21**, Purchase, NY

Company is a supplier to GNC. Performed consulting work regarding their products.

1996 **Nutramerica**, Lincoln Park, NJ

Technical advisor for the development of a dietary supplement product line.

CORPORATE CONSULTING EXPERIENCE (continued)

1996 **American Vitamin**, Ramsey, NJ

Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

COLLEGE TEACHING EXPERIENCE

2013-2018 **Touro College,** New York City, NY

Taught in nursing school.Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014 **University of Medicine & Dentistry of New Jersey (UMDNJ)**, Newark, NJ

Taught innutrition program. Courses includedgeneral chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and **New York University,** New York, NY

2000-2003 Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012 **Cedar Crest College**, Allentown, PA

Taught courses in nutritional biochemistry and metabolism.

1984-1989 **University of New Haven**, West Haven, CT

Taught graduate level course in vitamin and mineral nutrition.

1974-1984 **Brooklyn College, CUNY**, Brooklyn, NY
Assistant Professor

Taught nutrition courses to pre-medical and nutrition students.

1973-1977 **Rutgers University**, Piscataway, NJ

Taught general biology lab and mineral metabolism.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC., et. al.

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

CERTIFICATE OF SERVICE

I certify that on September 27, 2022, I served the foregoing Plaintiff's Responsive Brief on Claim Construction Issues for Markman Hearing upon all parties herein by filing copies of same using the ECF System.

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